IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF ROBERT MIRAGLIUOLO TAKEN AUGUST 24/25, 2013

BSC Counter Designation	Objection	Plaintiffs Counter Designation to BSC Counter Designation
rm042413, (Pages 52:2 to 53:10) **52** **(Exhibit Number 141** **marked for identification)** **Q. This is a document that is entitled "Guidance** **for Preparation of a Premarket Notification Application** **for a Surgical Mesh." Correct?** **A. Correct.** **Q. And it's a guidance for industry and/or for FDA** **reviewers, staff and/or compliance. Correct?** **A. Correct.** **Q. This is not the first time you've seen this** **document. Right?** **A. Correct.**	**BSC has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in the counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

14 Q. And what's the date of the document? 15 A. March 2nd, 1999. 16 Q. What is the purpose of this kind of a document? 17 A. This is called a special controls under the 18 Class II regulations, and it's to provide guidance to 19 industry, the FDA reviewers, and FDA compliance on what 20 types of information industry should provide and FDA 21 should be looking for to assess a premarket notification 22 application for surgical mesh product. 23 Q. Put in an even more concise manner, it's FDA 24 telling you if you want a product cleared, this is what 53 1 you need to send us. 2 A. It's a guidance on it, yes. 3 Q. Right. 4 A. Correct. 5 Q. It helps you. You look at this document and 6 you know what to send the FDA to try and get a product 7 cleared. Right? 8 A. Correct. 9 Q. So they're kind of telling you what they want? 10 A. Correct.		
rm042413, (Pages 81:14 to 82:5) 81 14 Q. Which is a couple of weeks after you got the 15 letter from the FDA. Correct? 16 A. Correct. 17 Q. Was this document prepared for you to help you 18 respond to the FDA's question? 19 A. Let me read it. 20 Q. Sure. 21 (Pause) 22 A. I believe that's correct. 23 Q. Okay. So to summarize, you get a letter from 24 the FDA asking about Marlex. 82 1 A. Correct.	81:14-82:5 FRE 401, 402, 403 FDA	

2 Q. Doreen Rao in response to that letter prepares 3 a memorandum on the issue and gives it to you on 4 July 8th, 2008. Correct? 5 A. Correct.		
rm042413, (Pages 94:6 to 95:11) 94 6 Q. And then you flip over and you talk about the 7 safety testing that was done -- on the bottom you say 8 there were biocompatibility tests, about which you're 9 somewhat unfamiliar. Correct? 10 A. Correct. 11 Q. But then they're listed on the next page. 12 Right? 13 A. Correct. 14 Q. But those are tests that are for 15 biocompatibility, right? 16 A. (No verbal response) 17 Q. What is an Ames mutagenicity test? 18 A. As I stated earlier, I'm not an expert in this. 19 The company has experts in this area. 20 Q. But then it talks about here, it says, "In 21 addition, a rabbit implantation study was commissioned 22 by Boston Scientific to assess the safety of a Boston 23 Scientific polypropylene mesh from Marlex HGX-030-01. 24 Dr. Badylak's report dated January 13, 2003, confirmed 95 1 that the mesh made from Marlex HGX-030-01 had 2 physiological response comparable to the control 3 device, a competitive implantable mesh also made from 4 polypropylene (confirmed by FTIR)." 5 Did I read that correctly? 6 A. Correct. 7 Q. So the study -- You did some biocompatibility 8 tests, but the only study that was done in a living	94:6-95:11 FRE 401, 402, 403 FDA	

9 organism was the rabbit study. Correct? **10 A. Actually, I think some of the biocompatibility** **11 testing is also conducted in animals.**		
rm042413, (Page 95:17 to 95:24) **95** **17 Q. Okay. And that's not a clinical study, is it?** **18 A. It's an in vivo study.** **19 Q. Clinical studies are on humans. Correct?** **20 A. Correct.** **21 Q. So there was no clinical testing of the Marlex.** **22 Correct?** **23 A. Correct. However, there was a long history of** **24 the use of Marlex in humans.**	**95:17-95:24** **FRE 401, 402, 403**	***[Counter Designation to 95:17-95:24}]*** ***rm042413, (Page 95:7 to 95:16)*** ***95*** ***7 Q. So the study -- You did some biocompatibility*** ***8 tests, but the only study that was done in a living*** ***9 organism was the rabbit study. Correct?*** ***10 A. Actually, I think some of the biocompatibility*** ***11 testing is also conducted in animals.*** ***12 Q. Oh, guinea pigs and mice. Correct?*** ***13 A. Correct.*** ***14 Q. But the only study that was actually done was*** ***15 this rabbit study. Correct?*** ***16 A. Correct.***
rm042413, (Page 96:3 to 96:7) **96** **3 (Exhibit Number 147** **4 marked for identification)** **5 Q. This is an appendix to the Solyx 510(k). I'm** **6 being more space efficient, just giving you the** **7 appendix.**		***rm042413, (Page 96:8 to 96:10)*** ***96*** ***8 And if you flip over from the first page, it*** ***9 appears that this appendix is what's dealing with the*** ***10 Marlex issue. Correct?***
rm042413, (Page 97:2 to 97:8) **97** **2 Q. Now, one of the things that -- This agreement** **3 is the one that is referenced in the Doreen Rao memo,** **4 and it is also mentioned in the answer to the question** **5 that you provided to the FDA. Correct?** **6 A. The response says "Appendix D," and this says** **7 "Appendix F."** **8 Am I looking at the right document?**	**97:2-97:8** **FRE 401, 402, 403** **FDA**	
rm042413, (Page 101:6 to 101:11)	**101:6-101:11**	

101 6 Q. So the only study that was done was the rabbit 7 study, but you-all also did some biocompatibility 8 testing. Correct? 9 A. Correct. And I think there was also reference 10 to shelf-life testing on it, testing of the mechanical 11 properties of the mesh.	FRE 403	
rm042413, (Page 115:1 to 115:21) 115 1 Q. Do you think the testing was adequate. 2 A. Yes. 3 Q. Even though the only study was done in rabbits' 4 abdomens instead of women's vaginas? 5 A. Yes. 6 Q. Can you think of any reason why Boston 7 Scientific wouldn't study this product in women's 8 vaginas? 9 A. It's not in women's vaginas, but I'll take that 10 every time you say that to say transvaginal. 11 Q. Sure. 12 A. I think we believed that it wasn't necessary. 13 Marlex mesh had a long history of applications in the 14 human body. Very successful. And we complied with the 15 regulation requirements and FDA, who are very technical, 16 very scientific. 17 Every document that is sent to FDA is 18 reviewed by biocompatibility experts, sterilization 19 experts, clinical experts, physicians. And they, too, 20 agreed that our work was sufficient for them to grant us 21 clearance for those applications.	115:14-21 FRE 401, 402, 403 FDA	
rm042513, (Pages 450:17 to 453:11) 450 17 Q. Would you state your name, please. 18 A. Robert T. Miragliuolo. 19 Q. Would you just take a few minutes and tell the	BSC has previously designated this testimony. Plaintiffs	Plaintiffs adopt and incorporate their counter designations, if any.

20 jury -- introduce yourself to the jury and tell the jury 21 a little bit about yourself. 22 A. Yes. My name is Robert T. Miragliuolo. I'm 23 the vice president of regulatory affairs for the 24 Endoscopy and Urology and Women's Health business. 451 1 I grew up in Bangor, Maine. I went to local 2 schools there, grammar school and high school. My 3 parents instilled in me a work ethic at an early age. I 4 was working when I turned 15. I washed floors at a 5 hospital in the summers, and in the evenings I worked in 6 a shoe factory, a Tom McAn shoe factory and Bauer skate 7 factory. 8 On graduation from high school, I went to 9 Providence College where I majored in biology. During 10 the summers I returned to Maine and I worked on a 11 grounds crew at a medical center. 12 Q. What year did you graduate from Providence? 13 A. 1974. 14 Q. Okay. Go on. 15 A. On graduating from college, I returned to the 16 state of Maine where I had a number of jobs. I worked 17 on -- I was a -- I taught high school math, I was a 18 special tutor for the State of Maine where I tutored 19 kids who needed special assistance. 20 And in addition to that, I also had two little 21 businesses, a landscaping business in the summer and 22 also a painting -- house painting and small contracting, 23 a carpentry business.	adopt and incorporate their objections as set forth in their counter designations, if any.	

24 I then went to the University of Vermont in 452 1 biostatistics for my master's degree. While I was 2 there, I worked in the agricultural research station 3 working on agricultural experiments doing biostatistics 4 work on those. And I also had an appointment in the 5 medical school as a biostatistic statistician fellow, 6 where I worked on clinical trial information. 7 Q. Now, when you say "biostatistics," just give me 8 a sense for what that means. 9 A. Biostatistics is really the focus of using 10 statistical mathematics in fields associated with 11 biology. 12 (Exhibit Number 193 13 marked for identification) 14 Q. I've marked as Deposition Exhibit Number 19e a 15 current copy of your curriculum vitae. I think you've 16 already reviewed this and identified it as being 17 accurate. 18 You have worked for various companies who have 19 been producing medical devices for a number of years. 20 Is that right? 21 A. Correct. 22 Q. I want to focus your attention on your time at 23 Boston Scientific. Give the jury just a quick overview 24 of when you started at Boston Scientific and what your 453 1 responsibilities had been there at that company. 2 A. Yes. I joined Boston Scientific in late 1999. 3 I joined the Urology business -- it was only the Urology 4 business at that time -- as the vice president of		

5 regulatory and clinical affairs. 6 Shortly after I took that position, within six 7 months, the company made a decision that they were going 8 to separate regulatory from clinical. And as a result 9 of that, I took on -- I gave up the clinical 10 responsibility and took on responsibility -- regulatory 11 responsibility for the Endoscopy business at that time.		
rm042513, (Page 455:10 to 455:16) 455 10 Q. Generally speaking, Rob, describe for the jury 11 how many medical devices containing pelvic mesh have 12 been cleared by the FDA in the period of time that you 13 have been the vice president of regulatory for Boston 14 Scientific. 15 A. I think it's approximately nine different 16 products have been cleared.	BSC has previously designated this testimony. Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
rm042513, (Pages 456:16 to 457:14) 456 16 Q. Okay. Earlier yesterday there was a document 17 that was marked and identified as Exhibit 141, which is 18 entitled "Guidance for the Preparation of a Premarket 19 Notification Application for a Surgical Mesh." 20 And I don't want to spend too much time on 21 this, but just give the jury some sense for what is the 22 importance of this guidance document from the FDA for 23 purposes of a company like Boston Scientific seeking FDA 24 clearance for products containing surgical mesh. 457 1 A. This is a guidance document. It is considered 2 a special controls under the regulations. And it's for	BSC has previously designated this testimony. Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

3 Class II products whose pathway to market is the 510(k). 4 And this is a document that basically lays out 5 the information that FDA -- not only the FDA should ask 6 but also the guidance for industry to provide the 7 appropriate information that FDA feels is necessary for 8 them to make the decision to allow the product to be on 9 the market. 10 Q. And where does the safety and efficacy of the 11 product factor into those guidelines? 12 A. It factors into their substantial equivalence 13 statement in that this information is sufficient for 14 them to make that determination.		
rm042513, (Pages 466:6 to 467:10) 466 6 Q. I want to mark quickly one more document. I'll 7 mark this as Exhibit 195. 8 (Exhibit Number 195 9 marked for identification) 10 Q. And this is a different group. This is the 11 American Urogynecologic Society. 12 This exhibit states that "The American 13 Urogynecologic Society is a nonprofit organization of 14 over 1,500 physician and allied health members. AUGS 15 represents the largest professional society representing 16 Female Pelvic Medicine and Reconstructive Surgery 17 specialists." 18 Do see where I read that in the second 19 paragraph? 20 MR. OSBORNE: Form. Predicate. Leading. 21 A. Yes. 22 Q. What is the position as reflected in this 23 position statement of the -- a group called AUGS with	BSC has previously designated this testimony. Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

24 respect to the appropriateness of having POP devices 467 1 available for patients who may be appropriate 2 candidates? 3 MR. OSBORNE: Form, predicate. 4 A. I'll read it. "The American Urogynecologic 5 Society strongly opposes any restrictions by state or 6 local medical organizations, healthcare systems, or 7 insurance companies which ban currently available 8 surgical options performed by qualified and credentialed 9 surgeons on appropriately informed patients with pelvic 10 floor disorders."		
rm042513, (Pages 472:7 to 473:6) 472 7 Q. Okay. Let's shift gears a little bit. Let's 8 talk about FDA and FDA transparency. The jury may have 9 heard and seen e-mails and meetings and whatnot between 10 you and others on your regulatory team with the FDA. 11 Describe, first of all, the role of the FDA in 12 terms of reviewing our submissions and commenting on 13 them. 14 A. Okay. FDA has a very important, very difficult 15 role in the healthcare system. And one of them is 16 determining which products should be placed into 17 commercialization. 18 And how it's done is they -- the company 19 provides FDA a body of evidence and quite detailed 20 information. When that body of evidence is submitted to 21 FDA in the form of a 510(k), that review process at FDA 22 is conducted by multiple functions and FDA experts.	BSC has previously designated this testimony. Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

23 There's clinical folks, there's medical folks, there's 24 experts in biocompatibility, there's experts in 473 1 sterilization, there's experts in packaging. 2 And all of them review their -- that body of 3 evidence from their perspective. And should they have 4 any questions, they will provide those questions back to 5 the company and provide the company an opportunity to 6 respond to those questions.		
rm042513, (Pages 473:12 to 475:6) 473 12 Q. What input and what kind of regulations govern 13 what is in the directions for use? 14 A. The directions for use are -- is a critical 15 component of any submission to FDA, and it's one of 16 the main methods by which FDA controls devices. 17 So any information that's put into the 18 directions for use has to be reviewed and approved by 19 FDA prior to it being placed into -- alongside the 20 product into commercialization. 21 Q. Let me quickly identify what's been previously 22 marked as a direction for use in the Uphold. I think 23 you've previously identified this. 24 Is that what this appears to be, Exhibit 83? 474 1 A. Yes. 2 Q. And examples of what could be in the directions 3 for use include such things as? 4 A. There's the general caution statement that 5 states that this product can only be sold or used on the 6 order of a physician. And then you get into the	BSC has previously designated this testimony. Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

7 concepts of warnings. Those are explanation of things 8 that the user should be aware of. There's the intended 9 use statement, which is specific use of the product that 10 FDA has cleared. 11 There's a section called contraindications, 12 which are fairly critical. There's areas where it's 13 strongly recommended that the product not be used in. 14 There's another section called warnings and 15 potential complications that gives a long list of 16 potential complications that are possible to occur. 17 Q. Okay. 18 A. And this also provides instructions on how to 19 use the product. 20 Q. When you're talking about the FDA regulating 21 these words, these specific words, these categories of 22 information, contraindications, warnings, intended 23 use, indications for use, those are examples of what 24 you're talking about? 475 1 A. Yes. 2 Q. And we have examples here where our submissions 3 to the FDA invited comments and suggestions and 4 requested changes from the FDA on the terms of such 5 things as the directions for use? 6 A. Correct.		
rm042513, (Page 480:1 to 480:13) 480 1 Q. Counsel was -- he asked you a number of 2 questions about informed consent. Do patients and 3 doctors have sources of information about products and 4 about conditions and about surgery options? 5 MR. OSBORNE: Form, predicate.	BSC has previously designated this testimony. Plaintiffs adopt and incorporate their	Plaintiffs adopt and incorporate their counter designations, if any.

6 A. Absolutely, yes. **7 Q. Let's talk about doctors. What are sources of** **8 information to doctors in addition to the directions for** **9 use that we've just identified?** **10 A. There is the literature. There's also various** **11 society -- medical societies that they can obtain** **12 additional information from. And there's also the** **13 Internet, which also has a wealth of information on it**	**objections as set forth in their counter designations, if any.**	
rm042513, (Page 501:19 to 501:23) **501** **19 Q. Counsel showed you earlier Exhibit 153. This** **20 is a document that related to ProteGen. Do you recall** **21 this document?** **22 A. Yes.** **23 Q. This reflects a draft. And I think you told**	**Completeness**	***rm042513, (Pages 501:24 to 502:2)*** ***501*** ***24 the jury that on April 22, 1999, you had not yet even*** ***502*** ***1 started working at the company.*** ***2 A. That's correct***
rm042513, (Pages 503:1 to 504:10) **503** **1 A. That the ProteGen rate was high but the current** **2 products on the market have a very acceptable erosion** **3 rate.** **4 Q. Let's talk a little bit about, quickly, the** **5 MSDS sheet. Are you familiar with that?** **6 A. Yes.** **7 Q. What does that mean? What's MSDS?** **8 A. Material safety data.** **9 Q. And the MSDS sheet was submitted as part of our** **10 510(k) submissions, as we do with raw materials, to the** **11 FDA?** **12 A. Yes.** **13 Q. And over time did the MSDS sheet evolve and** **14 change?** **15 A. Yes.** **16 Q. How?** **17 A. There was a change in ownership of the**	**503:1-3** **FRE 401, 402, 403** **FDA, Misleading** **Completeness** **Foundation** **503:9-12** **FRE 401, 402, 403** **FDA**	***rm042513, (Page 502:17 to 502:23)*** ***502*** ***17 Q. And if you accept the FDA -- the summary of the*** ***18 advisory committee panel that I showed you earlier that*** ***19 said that the average erosion rate for stress urinary*** ***20 incontinence devices was less than 5 percent --*** ***21 A. Yes.*** ***22 Q. -- that would obviously represent what, in your*** ***23 mind?***

18 material, and the new owner was unwilling to take on the 19 liability associated with using this material in medical 20 device products. 21 These companies manufacture large volumes of 22 this material and only a very small portion of it is 23 used in medical devices. And they were unwilling to 24 accept the liability associated with doing that. 504 1 Q. Directing your attention to Exhibit 146, does 2 this reflect -- and I believe you've already discussed 3 the open discussion with the FDA about the statement on 4 the MSDS sheet in which the FDA specifically quotes that 5 "Do not use this Chevron Phillips Chemical Company LP 6 material in medical applications involving permanent 7 implantation in the human body or permanent contact with 8 internal body fluids or tissues." 9 They ask for our explanation, and we give it. 10 A. Correct.	504:1-10 FRE 401, 402, 403 FDA	
rm042513, (Page 504:12 to 504:20) 504 12 A. We provide them the entire chronology of events 13 there. 14 Q. And what was the FDA's response? 15 A. Their response was they cleared our 510(k). 16 Q. Is Marlex -- does it remain a component of the 17 stress urinary incontinence slings that have been 18 declared by the advisory committee panel to be safe and 19 effective? 20 A. Yes.	504:12-504:20 FRE 401, 402, 403 FDA	
rm042513, (Pages 504:22 to 505:2) 504	504:22-505:2 FRE 401, 402, 403	

22 Q. In other words, that same raw material is what **23 makes up the stress urinary incontinence slings that the** **24 advisory committee panel believes no further evidence is** **505** **1 needed of their safety and effectiveness?** **2 A. Correct.**		
rm042513, (Page 507:4 to 507:19) **507** **4 Did Boston Scientific know and follow the** **5 regulatory rules to demonstrate the safety and** **6 effectiveness of its pelvic mesh products?** **7 A. Yes.** **8 Q. Did the FDA review the scientific evidence,** **9 review your testing to reach a conclusion as to whether** **10 or not we had met the standards?** **11 A. Yes.** **12 Q. Are there many occasions of the FDA requesting** **13 meetings, having calls, sending us letters, sending us** **14 e-mails, asking for additional information on a whole** **15 variety of topics related to our pelvic mesh products?** **16 A. Yes.** **17 Q. And in every case the submissions that we made** **18 were ultimately cleared by the FDA?** **19 A. Yes.**	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

1. **Objections to Counter Exhibits.**

   a. Miragliuolo 141 and 195 have been previously identified by BSC. Plaintiffs adopt and incorporate their objections to these exhibits as set forth in the counter designations, if any.

DATED: July 20, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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